K061755

510(k) Summary

AUG - 7 2006

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Carri Graham, Official Correspondent
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Contact Person: Carri Graham

Date: June 21, 2006

807.92(a)(2)

Trade Name:	MyLab15/20 New Indications Ultrasound System	
Common Name:	Ultrasound Imaging System	
Classification Name(s):	Ultrasonic pulsed echo imaging system	892.1560
	Ultrasonic pulsed Doppler imaging system	832.1550
Classification Number:	90IYO	
	90IYN	

807.92(a)(3)

Predicate Device(s)

K014168	Technos	Esaote, S.p.A.
K043588	MyLab15/20 Ultrasound System	Pie Medical
K053154	MyLab15/20 Just3D/4D	Pie Medical

Additional Substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

510(k) Summary
MyLab15/20
Esaote Europe BV

K061755

[redacted]

807.92(a)(4) **Device Description**

The MyLab15/20 is a compact console ultrasound system used to perform general diagnostic ultrasound studies. Its primary modes of operation are: B-Mode, M-Mode, PW Doppler and Color Flow Mapping and Tissue Enhancement Imaging (TEI). MyLab15/20 is able to produce real time 2D images and 3D images (in manual mode) with all probes. The system, in combination with the probe BC432P, offers the possibility to also produce automatic 3D and real time 4D images

807.92(a)(5) **Intended Use(s)**

Esaote's MyLab15/MyLab20 is a compact console ultrasound system intended to be used by a physician to perform general diagnostic ultrasound studies including Fetal, Abdominal, Pediatric, Small organ, Neonatal Cephalic, Cardiac, Transrectal, Transvaginal, Peripheral Vascular, Intraoperative: Abdominal, Other: Urological, Musculoskeletal (Conventional and Superficial).

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Comparison Chart for Substantial Equivalence

General Characteristics	Esaote MyLab15/20 K043588, K053154	Esaote Technos K014168	Esaote MyLab15/20 Current 510(k)
Applications			
Intraoperative: Abdominal	**No**	**Yes**	**Yes**
Other: Urological	**No**	**Yes**	**Yes**

~~K043588~~ K061755

General Characteristics	Esaote MyLab15/20 K043588, K053154	Esaote Technos K014168	Esaote MyLab15/20 Current 510(k)
Transducer Type			
Linear	**Yes**	**Yes**	**Yes**
Convex	**Yes**	**Yes**	**Yes**
2D Freq MHz	**2.7 – 15**	**2.8 – 12.5**	**2.7 – 15**
Multifrequency	**Yes**	**Yes**	**Yes**
Special probes	• Endocavity probe • Mechanically Driven 3D Convex Array	• Endocavity probe • Mechanically Driven 3D Convex Array • CW Doppler Probe	• Endocavity probe • Mechanically Driven 3D Convex Array
Biopsy attachments			
Convex	**Yes**	**Yes**	**Yes**
Linear	**Yes**	**Yes**	**Yes**
Imaging modes			
Real Time 2D	**Yes**	**Yes**	**Yes**
M-mode	**Yes**	**Yes**	**Yes**
PW Doppler	**Yes**	**Yes**	**Yes**
CW Doppler	**No**	**Yes**	**No**
CFM Doppler	**Yes**	**Yes**	**Yes**
Amplitude Doppler	**Yes**	**Yes**	**Yes**
Triplex	**Yes**	**Yes**	**Yes**
3D/4D	**Yes**	**Yes**	**Yes**
Monitor size (inches)	• **15" CRT monitor** • **15" LCD**	**15" Color VGA CRT Monitor**	• **15" CRT monitor** • **15" LCD** • **19" LCD**
ECG	**Optional**	**Optional**	**Optional**
Digital archival capabilities	**Yes**	**Yes**	**Yes**
VCR & Video printers	**Yes**	**Yes**	**Yes**
M&A capabilities	**Yes**	**Yes**	**Yes**
Safety			
Electrical safety	**EN60601-1**	**EN60601-1**	**EN60601-1**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG - 7 2006

Esaote Europe BV
% Ms. Carri Graham
Consultant
The Anson Group
11460 N Meridian St, Ste 150
CARMEL IN 46032

Re: K061755
Trade Name: MyLab 15/MyLab 20 Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: IYO, IYN, and ITX
Dated: June 19, 2006
Received: June 21, 2006

Dear Ms. Graham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the MyLab 15/MyLab 20 Systems, as described in your premarket notification:

Transducer Model Number

IOE323
CA123
C5-2 R13

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain

other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Ralph Shuping at (301) 594-1212.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K061755

Device Name: MyLab15/MyLab20 Systems

Indications For Use:

Esaote's MyLab15/MyLab20 is a compact console ultrasound system intended to be used by a physician to perform general diagnostic ultrasound studies including Fetal, Abdominal, Pediatric, Small organ, Neonatal Cephalic, Cardiac, Transrectal, Transvaginal, Peripheral Vascular, Musculoskeletal (Conventional and Superficial), Intraoperative: Abdominal, and Other: Urological.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lejnar

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061755

K061755

MyLab15/20 Systems

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P	P		P [2]	P[3], P[4], P[5]
Abdominal		P	P	P		P	P		P [2]	P[3], P[4], P[5]
Intraoperative Abdominal		N	N	N		N	N		N[2]	N[3], N[4]
Intraoperative Neurological										
Pediatric		P	P	P		P	P		P [2]	P[3], P[4], P[5]
Small Organ (specify) [1]		P	P	P		P	P		P [2]	P[3], P[4]
Neonatal Cephalic		P	P	P		P	P		P [2]	P[3], P[4]
Adult Cephalic										
Cardiac		P	P	P		P	P		P [2]	P[3]
Transesophageal										
Transrectal		P	P	P		P	P		P [2]	P[3], P[4]
Transvaginal		P	P	P		P	P		P [2]	P[3], P[4]
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P		P [2]	P[3], P[4]
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P		P [2]	P[3], P[4]
Musculo-skeletal Superficial		P	P	P		P	P		P [2]	P[3], P[4]
Other: Urological		N	N	N		N	N		N[2]	N[3], N[4]

N=new indication; P=previously cleared by FDA; E= added under Appendix E

Additional Comments:

[1] Small organs include Thyroid, Breast and Testicles.
[2] Applicable combined modes: B+M+PW+ CFM+Amplitude Doppler
[3] Tissue Enhancement Imaging (TEI)
[4] 3D Imaging
[5] 4D Imaging

David R. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061755

K061755

IOE323

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N		N	N		N [2]	N [3]
Intraoperative (Adominal)		N	N	N		N	N		N [2]	N [3]
Intraoperative Neurological										
Pediatric										
Small Organ (specify) [1]		N	N	N		N	N		N [2]	N [3]
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N [2]	N [3]
Laparoscopic										
Muscolo-skeletal Conventional		N	N	N		N	N		N [2]	N [3]
Muscolo-skeletal Superficial		N	N	N		N	N		N [2]	N [3]
Other										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

[1] Small organs include Thyroid, Breast and Testicles.
[2] Applicable combined modes: B+M+PW+CFM+PD
[3] Tissue Enhancement Imaging (TEI)

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concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061755

K061755

CA123

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N		N [2]	N [3]
Abdominal		N	N	N		N	N		N [2]	N [3]
Intraoperative (Adominal)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify) [1]		N	N	N		N	N		N [2]	N [3]
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N		N	N		N [2]	N [3]
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N [2]	N [3]
Laparoscopic										
Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial										
Other: Urological		N	N	N		N	N		N [2]	N [3]

N= new indication; P= previously cleared by FDA; E= added under Appendix E

[1] Small organs include Thyroid, Breast and Testicles.
[2] Applicable combined modes: B+M+PW+CFM+PD
[3] Tissue Enhancement Imaging (TEI)

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concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061755

K061755

C5-2 R13

Clinical Application	Mode of Operation									
	A	B	M	PWD (PW)	CWD (CW)	Color Doppler (CFM)	Amplitude Doppler (PD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N	N		N [2]	N [3]
Abdominal		N	N	N		N	N		N [2]	N [3]
Intraoperative (Adominal)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify) [1]		N	N	N		N	N		N [2]	N [3]
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N		N	N		N [2]	N [3]
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N		N [2]	N [3]
Laparoscopic										
Muscolo-skeletal Conventional										
Muscolo-skeletal Superficial										
Other: Urological		N	N	N		N	N		N [2]	N [3]

N= new indication; P= previously cleared by FDA; E= added under Appendix E

[1] Small organs include Thyroid, Breast and Testicles.
[2] Applicable combined modes: B+M+PW+CFM+PD
[3] Tissue Enhancement Imaging (TEI)

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concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A Seyman

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510(k) Number K061755